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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,288	05/29/2001	David K. Swanson	15916-069x	8100

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,288	SWANSON ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44,46-50 and 148-154* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44, 46-50 and 148-154* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and comments, received July 11, 2006, have been fully considered by the examiner. In particular, applicant's decision to amend the claims and not pursue the request for interference is noted. The following is a complete response to the July 11, 2006 communication.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44, 46-50 and 148-154 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to recite that the device has an expanded size and shape that corresponds to a circumferential region of an orifice of a vein that carries blood to an atrium. In short, applicant is now claiming that the ablation device is approximately the size of a single pulmonary. There is no support in the specification for such a limitation. Page 46 of the specification addresses Figure 13, and contains the only description of making a circumferential lesion surround pulmonary veins. In particular, it is noted that lines 23-25 indicate that the hoop device (42(6)) differs from the basket device in that it forms a single hoop. It is noted that the previous basket hoops are large and used to map and ablate tissue of the entire atria (see Figure 24 showing the basket with hoop members

(42) taking up substantially the whole atria). There is no disclosure that the hoop in the embodiment of Figure 13 is much smaller than the previously disclosed embodiments to allow for the creation of a lesion around a singular pulmonary vein. Moreover, the language at lines 26-30 on page 46 states that the device may form lesions "that substantially encircle the orifices of the SVC 26 and the IVC 28 in the right atrium 12 and the PV's 30 in the left atrium 14". The examiner's position is that this is not a disclosure of creating lesions around singular veins. Rather, this disclosure suggests that a lesion may be made around the SVC and IVC in the right atrium, or around all the PV's in the left atrium.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 44, 46-50 and 148-154 are rejected under 35 U.S.C. 102(e) as being anticipated by Avitall (5,263,493).

Avitall discloses a tissue ablation device for use the chambers of the heart. The device comprises an elongate member (18) adapted to be positioned adjacent to a circumferential region of tissue, and an ablation element (28) comprising a loop with a plurality of electrodes (36) that is adapted to form a lesion in a circumferential region of tissue. As seen in the figures, the ablation element is a loop (Figures 2 and 6) that is of a size and shape adapted to surround pulmonary veins in the atrium. Note column 4, lines 20-30 where Avitall discloses the device may be used to map atrial and ventricular tissue. Avitall also discloses various dimensions for the device to support its use in

atrial mapping around pulmonary veins. The loop structure is collapsible (Figure 2B). Figure 4 shows an actuation element to control the shape and deployment of the ablation loop, and no fluid is delivered to tissue during the ablation procedure.

This rejection is maintained in the event applicant asserts the newly amended claims are not specifically claiming the creation of lesions around singular PV's as appears to be the intent.

Response to Arguments

Applicant's arguments filed July 11, 2006 have been fully considered but they are not persuasive.

Initially, it is noted that there is a certain level of ambiguity in the claim language. It is not entirely clear what the language "defining an expanded size and shape that corresponds to a circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium" describes. The examiner's position in the previous Office action is that a device that is large enough to encircle all the PV's would read on such language. The examiner maintains that this is a fair interpretation of the language, and that applicant's originally filed specification supports that the invention is used in this manner. However, applicant appears to be arguing that the device creates a lesion around a single PV. As asserted in the above 35 USC 112 rejection, the examiner maintains there is no support for this basis of argument. The claims have been rejected under both interpretations of the language (i.e. a lesion around all the PV's, or a lesion around individual PV's) in view of this ambiguity.

Applicant asserts on page 6 of the response that the Office action has not shown that a size and shape that corresponds to a tricuspid annulus (i.e. the size and shape of the Avitall device) also corresponds to a circumferential region of tissue associated with a vein that carries blood to the atrium. Clearly, the Avitall device is capable of creating a circumferential lesion. Further, Avitall specifically disclose the device may be used for atrial and ventricular mapping. Finally, given the dimensions of the tricuspid annulus is larger than the dimension of a pulmonary vein, the Avitall device is clearly capable of surrounding one or more pulmonary veins in an atrium. Avitall also disclose the dimensions of the electrodes and the support member, which dimensions would clearly facilitate the device being used to surround the pulmonary veins.

As asserted in the 35 USC 112, first paragraph rejection, the examiner maintains that there is insufficient disclosure to support applicant's invention surrounding a singular PV (or the SVC or the IVC). The device as disclosed clearly appears to be a large loop structure commensurate in size with the basket member that takes up substantially the entire atrium (Figure 24). As such, the claimed invention is deemed to be comprised of a large loop member that would surround substantially the entire atrium and would surround all the PV's if inserted into the left atrium, or would surround both the SVC and the IVC when inserted into the right atrium.

The Avitall reference is essentially the equivalent structure as set forth in applicant's means-plus-function language of claims 148, 150 and 153. It consists of a catheter, and a collapsible loop structure having energy emitting electrodes capable of creating a lesion around tissue, the electrodes connected to an energy source. There is

an insubstantial difference between applicant's disclosed means as shown in Figure 13 and the Avitall loop structure shown in the figures. Again, the size of applicant's ring is deemed to be of a size for mapping and ablating the atrium wall, just at the Avitall loop structure may be used to map and ablate the atrium wall. Avitall discloses electrode and support member dimensions that support the loop is large enough to encircle the PV's of the left atrium and be used in the manner suggested in applicant's claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
August 8, 2006